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⑪ Publication number:

0 010 812  
A1

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## EUROPEAN PATENT APPLICATION

⑬ Application number: 79200623.1

⑮ Int. Cl.3: A 61 F 5/47

⑭ Date of filing: 26.10.79

⑩ Priority: 26.10.78 NL 7810696

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⑭ Date of publication of application: 14.05.80  
Bulletin 80/10

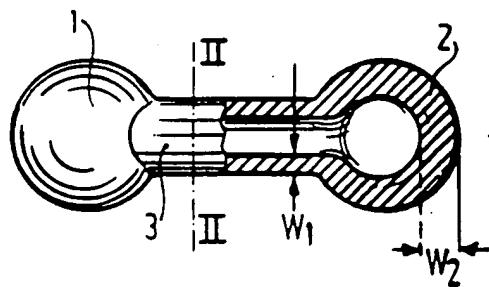
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⑯ Designated Contracting States: AT BE CH DE FR GB IT  
LU NL SE

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⑮ Contraceptive device.

⑯ Contraceptive device for intra uterine application in  
the oviducts having two enlargements 1, 2 connected by  
an oblong connection element 3 to a halter shape which  
enlargements remain fixed in the muscle tissues since the  
surface areas of the projections of these enlargements on  
a plane transverse to the longitudinal axis of the device  
are almost equal.



EP 0 010 812 A1

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Title: Contraceptive device

The invention relates to a contraceptive device for intra uterine application having an oblong connection element connecting two separate enlargements having rounded shapes. A contraceptive device of this kind is disclosed in Dutch Patent Application 74 01380 and comprises an oblong elastic slightly curved element having club shaped enlargements at either end. The remote sides of these enlargements are semi spherical and the adjoining sides gradually merge into the connection element. The enlargements each are to be positioned in the opposite oviducts but cannot suitably be fixed therein. Moreover is the distance between the funnel shaped mouths of the opposite oviducts in the uterus not constant such that either an insufficient closure or an excessive pressure on the tissues surrounding the enlargements is the result. The changes in distance can be partly compensated by making the connection element, having a length of some centimetres, curved and of a flexible material, but this is not reliable.

Object of the invention is to provide an improved contraceptive device which can be reliably positioned and fixed in the oviducts since the enlargements and the oblong connection element are of a dumb-bell shape and the surface areas of the projections of these enlargements on a plane transverse to the longitudinal axis of the device are almost equal, and the enlargements abruptly merging into the connection element.

This contraceptive device is to be positioned such

that one of the enlargements is just in the oviduct mouth and the other in the oviduct on the outside of the muscle tissue of the uterus.

For obtaining a good closure of the oviducts 5 while preventing an appreciable irritation the enlargements having a diameter of from 2-6 mm, the sandwiched connection element being 2-14 mm long and having a thickness amounting 0,4 - 0,8 times the largest diameter of the enlargements is to be preferred. In order to follow temporary dilatation 10 of the oviducts the enlargements preferably are at least partly made of rubber elastic material.

If the dilatations of the oviducts are prolonged these can be compensated by the contraceptive device provided at least part of it is having a circular layer of 15 a material which can highly expand by water absorption. An example of such material is an hydrogel, particularly polyhema, that is to say poly(hydroxyethyl)methacrylate. Preferably the contraceptive device is at least partly hollow and open at one end only. In a suitable embodiment the 20 entire device is made of a similar by moisture highly expandible material.

The axial fixation of the device will in an important degree be the result of the forces exerted by the muscle tissue of the uterus on the facing surfaces of 25 the enlargements. The closure predominantly takes place at the largest diameter of the enlargements, but also in a not neglectible degree by the pressure exerted by the muscle tissue of the uterus on the oblong connection element. This closure can be improved by providing the connection element 30 with at least one circular rib, which of course has a smaller diameter than the enlargements.

The invention will be explained in connection with the drawing in which some preferred embodiments of the contraceptive device and its use are depicted.

35 Fig. 1 shows a partly axial sectioned contraceptive device.

Fig. 2 shows a transverse section along the line II-II in fig. 1.

Fig. 3 and 4 show axial sections of modified embodiments of the device shown in fig. 1.

Fig. 5 shows the use of the contraceptive device according to the invention.

5 Fig. 6 shows an axial section of a modified embodiment of the device shown in fig. 1.

The contraceptive device as shown in fig. 1 comprises two spherical enlargements 1, 2 and a cylindrical oblong connection element 3. The device is entirely hollow.  
10 The wall thickness  $w_1$  of the connection element and the wall thickness  $w_2$  of the enlargements are dependent on the required elasticity of such parts.

In the depicted embodiment the ratio between the diameter  $d$  of the connection element 3 and the diameter  $d$  (capital) of the enlargements 1, 2 is about 0,5, but this ratio can be varied in dependence on the circumstances from 0,4 to 0,8. A smaller ratio will prevent a seal on the connection element and a larger ratio will increase the risk of axial rejection from the mouth of the oviducts if an 20 unequal muscle contraction occurs. The values of these diameters  $d$  (capital) and  $d$  and of the lengths  $l$  of the connection element will be dependent on the anatomic shape of the mouths 28 of the oviducts in the uterus and on the diameters of the oviducts just outside the uterus wall.

25 In fig. 5 the position of the contraceptive devices in the oviduct mouths 28 is shown: one of the enlargements still in the funnel shaped widened part 4 of the oviduct 5 in the uterus cavity and the other enlargement just outside the muscle tissue 7 of the uterus 30 8 in the oviduct. The several dimensions of the contraceptive device, particularly the length  $l$  of the connection element 3 have to be selected dependent on the anatomic data, in order that a suitable closure on all parts of the contraceptive device is obtained. The closure in the mouths 35 28 may be improved by providing the connection element with at least one circular rib as depicted in figs. 3 and 4. In fig. 3 the oblong element 9 is elliptic in longitudinal section, while in fig. 4 the oblong element 10 has three peri-

peripheral ribs 11 with rounded shapes for preventing tissue irritation.

Just like the embodiment as shown in fig. 1 that of fig. 3 is hollow, although in the latter case the internal cavity 12 debouches at one end through an opening 13 to the atmosphere enabling measuring instruments to be accommodated in the cavity and applying tools to grip in it.

The embodiment of fig. 4 is also different from that of fig. 1 in that a layered construction is used: the outer layer 14 may be a tissue friendly material, which property is not required for the material of the inner layer 15, which material may be chosen for its mechanical properties such as a certain elasticity.

The contraceptive device preferably is of at least an outer material which can highly increase in volume by water absorption, such as a hydrogel, offering the advantage that on dilatation of the cavity accomodating the device diameter increase will result by water absorption, so that the closure is safeguarded. By pressure increase after diameter decrease that material can loose water so that after a certain time the pressure exerted by the device on the surrounding tissues has an acceptable value again. Adapting the pressure is possible by a suitable selection of the materials of both layers and a selection of the wall thickness w 3 and w 4 of the inner layer 15 of the connection element and the enlargements respectively and the wall thickness w 5 and w 6 of the outer layer 14 of these parts.

In fig. 6 an axial section through a modified embodiment is shown, comprising an asymmetric core 20 made of copper and being rotary symmetric around its longitudinal axis. The core comprises a connection element 21 and two enlargements at its two ends. The one enlargement 21 is slightly pointed at its free end for easier application, the other enlargement 22 being flattened at its free end and having an axial bore 23 for applying tools to grip in.

The core is all round coated with a layer of polyhema 24. Despite the asymmetric shape this embodiment satisfies the requirement that the surface areas of the

projections of both enlargements on a plane 25 transverse to the longitudinal direction have to be equal.

It may be evident that the contraceptive devices shown in fig. 3 and 6 are positioned with the opening 13, 23 respectively towards the uterus cavity 6.

Claims

1. Contraceptive device for intra uterine application having an oblong connection element connecting two separate enlargements having rounded shapes characterised in that the enlargements and the connection element are of a dumb-bell shape and that the surface areas of the projections of these enlargements on a plane transverse to the longitudinal axis on a plane transverse to the longitudinal axis of the device are almost equal, the enlargements abruptly merging into the connection element.

10 2. Contraceptive device of claim 1, characterised in the enlargements having a diameter of from 2-6 mm, the sandwiched connection element being 2-14 mm long and having a thickness amounting 0,4 - 0,8 times the largest diameter of the enlargements.

15 3. Contraceptive device of claim 1, characterised in at least part of it being provided with at least a circular layer of a material which can highly expand by water absorption.

4. Contraceptive device of claim 1, characterised 20 in that the entire device is made of highly expandible material.

5. Contraceptive device of claim 3, characterised in the expandible material being a hydrogel.

6. Contraceptive device of any claim 1-5, characterised 25 in the expandible material being polyhema.

7. Contraceptive device of any claim 1-6, characterised in the enlargements having a copper containing core.

8. Contraceptive device of any claim 1-7,  
characterised in the enlargements at least partly being of  
rubber elastic synthetic resin.

9. Contraceptive device of any claim 1-8, charac-  
5 terised in the oblong connection element being provided with  
at least one circular rib having a smaller diameter than  
that of the enlargements.

10. Contraceptive device of any claim 1-9, charac-  
terised in the device being hollow and open at one end  
10 only.

FIG.1

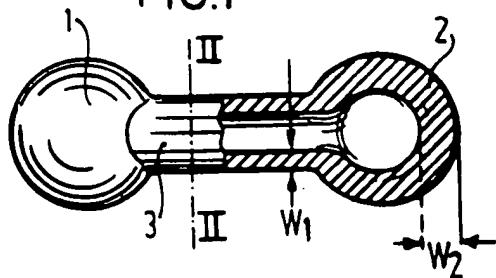


FIG.2

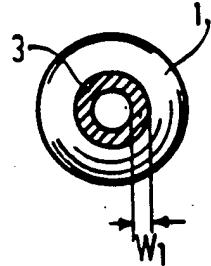


FIG.3

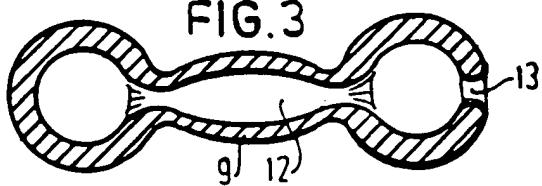


FIG. 6

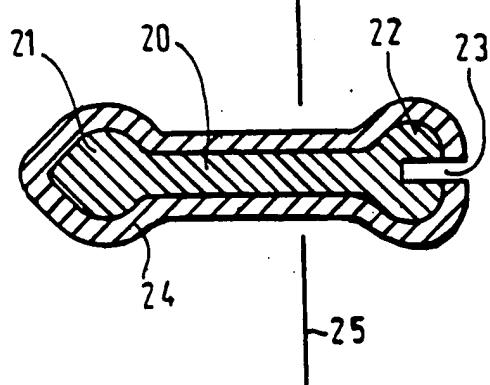
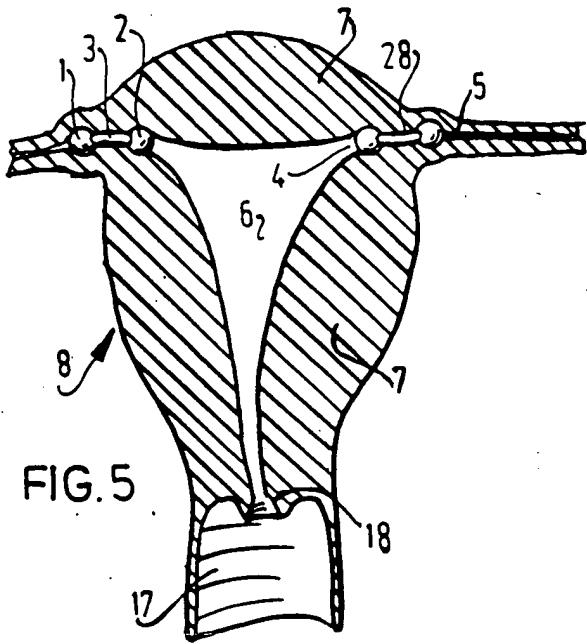
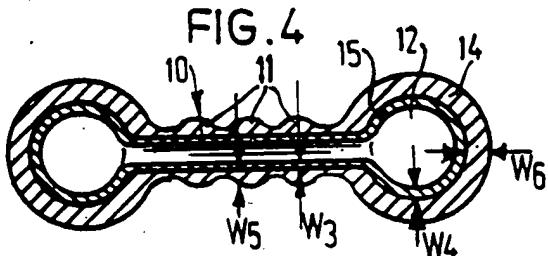


FIG.4





DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl. 3)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
	<p><u>DE - A - 2 328 175</u> (BLEIER) * Claims 1,4; figures *</p> <p>--</p> <p><u>DE - A - 2 537 620</u> (POPP) * Page 3, lines 17-30 *</p> <p>--</p> <p><u>US - A - 3 405 711</u> (BAKUNIN) * Column 1, line 46 - column 3, line 2; figures 1,3 *</p> <p>--</p> <p><u>NL - A - 67 09780</u> (SIEDERS) * Page 2, lines 42-48; page 4, lines 24-40 *</p> <p>--</p> <p><u>FR - A - 2 263 738</u> (BENNE) * Page 2, lines 31,32; figures *</p> <p>--</p>	1,8,10 1,10 1,10	A 61 F 5/47
A	<p><u>US - A - 3 805 767</u> (ALLAN) * Abstract; figure 2 *</p> <p>&amp; <u>NL - A - 74 02502</u></p> <p>--</p>	1	TECHNICAL FIELDS SEARCHED (Int.Cl. 3)
P	<p><u>NL - A - 78 01015</u> (AKTIE-BOLAGET MEDLINE) * Figures; claims 1-3 *</p> <p>----</p>	7	A 61 F A 61 K
<p>X</p> <p>The present search report has been drawn up for all claims</p>			CATEGORY OF CITED DOCUMENTS
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Place of search	Date of completion of the search	Examiner	
The Hague	22-01-1980	STEENBAKKER	